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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,925	03/06/2002	Toshio Kitamura	06501-102US1	1474
26161	7590	07/20/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,925	Applicant(s) KITAMURA ET AL.	
	Examiner Janet L. Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,15,16 and 18-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,5,7,9,13,28-32,34,35,37,39,40,42,43 and 50-53 is/are allowed.
- 6) ☒ Claim(s) 2,6-8,10,14-27,33,36,38,41 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 3 and 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 26 April 2004 is acknowledged. Claims 1-53 are pending in this application. Claims 11, 12, 15, 16, and 18-21 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the priority claim is withdrawn in response to Applicant's showing of enablement (see below).
3. The objection to the specification as using trademarks is withdrawn in response to Applicant's amendment capitalizing the trademarks.
4. The rejection of claims 1-10, 13, 14, and 17 under 35 U.S.C. 101 as lacking utility is withdrawn in response to Applicant's indication of post-filing date art showing that the mouse TSG-like protein does have the BMP binding function predicted by Applicant.
5. The rejection of claims 1-10, 13, 14, and 17 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility is withdrawn for the reasons set forth in paragraph 4 above.
6. The rejection of claims 1-10, 13, and 14 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims and as lacking written description is withdrawn in response to Applicant's amendment limiting the scope of claim 1, 4, 5, 7, 9, and 13 and providing functional limitations for claims 2, 3, 6, 8, 10, and 14.
7. The rejection of claims 1, 3-5, 7, and 9 under 35 U.S.C. 112, second paragraph, as indefinite in encompassing molecules identified by stringent hybridization and in the

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recitation of “functionally equivalent” is withdrawn in response to Applicant’s amendment deleting these terms.

8. The rejection of claims 1, 5, 7, 9, and 13 under 35 U.S.C. 102(b) is withdrawn in response to Applicant’s amendment limiting the scope of these claims. The rejection of claims 2, 6, 8, 10 under 35 U.S.C. 102(b) is withdrawn in response to Applicant’s arguments that these claims are limited to polynucleotides encoding SEQ ID NO: 2 and fragments of that molecule.

Claim Rejections Maintained/New Grounds of Rejection

9. The rejection of claim 17 under 35 U.S.C. 112, first paragraph, as lacking enablement and written description is maintained for reasons of record in the office action of 23 October 2003.

Applicant argues that this claim has been amended to recite specific hybridization conditions. However, the claim has no functional limitations. It must only be of at least 15 nucleotides and hybridize to Applicant’s disclosed polynucleotide or its complement. Thus the claim encompasses molecules that can be of any length and can vary substantially in structure and function from that disclosed by Applicant. Thus, for the reasons set forth in the previous office action, it would require undue experimentation for the skilled artisan to make and use this disparate group of molecules.

With respect to the rejection of the claim as lacking written description, Applicant points to example 9 of the training materials. This example has a functional limitation.

10. Claims 22-27, 33, 36, 38, and 41 are rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of “has an activity for rescuing aberrations in the

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differentiation of dorsal midline cells” and “an activity that regulates embryo development”.

There is no limitation as to what aberrations could be “rescued”, what activity such a “rescue” would involve, and no description as to what an activity that “regulates” embryo development would be. The claimed activity of the encoded protein could be anything involved in differentiation of the dorsal midline cells and anything involved in development. No activity is excluded. Thus one of skill in the art would not be able to determine what activities, and thus what encoding polynucleotides, Applicant intended the claims to encompass.

11. Claims 2, 6, 8, 10, and 14 are rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of “wherein the fragment ... encodes a protein”. The fragment referred to is a protein.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claim 17 under 35 U.S.C. 102(b) as anticipated by the ‘022 patent is maintained as a rejection under 35 U.S.C. 102(e) for reasons of record in the previous office action and applied to new claims 22, 23, 27, 33, 36, 38, 41, 45, and 46.

Applicant argues that the patent issued after Applicant’s claimed priority date. Applicant’s provision of post-filing date teachings indicating that the encoded TSG-like

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protein has the predicted function of BMP binding results in the withdrawal of the denial of priority. Thus priority is now granted to the PCT document of which the application is a continuation-in-part, and the benefit claim to the Japanese patent application is granted. Thus the '022 patent, which issued in December 1999 but has a priority date of 1996, is a later published patent filed before the invention by Applicant and the claims are now rejected under 35 U.S.C. 102(e).

Applicant argues that there is no teaching in the '022 patent that the polynucleotide disclosed in that patent would hybridize to that of Applicant. Applicant's arguments have been fully considered but have not been found to be persuasive. The ability to hybridize is an inherent property of closely related molecules. That the patent does not disclose an inherent property does not indicate that said property is not present; it need not be recognized by the artisan in order to exist. A technical reason has been provided: the sequences are closely related and closely related sequences hybridize to each other.

With respect to Applicant's arguments with respect to claim 45, that the '022 patent does not disclose Applicant's claimed function, the '022 patent discloses a polynucleotide that meets the structural limitations of Applicant's claims. MPEP §2112.01 states:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

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Applicant has not shown why a polynucleotide meeting the structural limitations of Applicant's claims would not have the function claimed by Applicant.

New claims 22, 33, and 38 are anticipated by the '022 patent because they encompass molecules identified by hybridization and because the '022 polynucleotide encodes a protein with 15 or fewer substitutions in the specified region and that is at least 90% identical to SEQ ID NO: 2 as well as to the specified region. Claim 23 is anticipated because the '022 polynucleotide encodes a sequence 5 or fewer substitutions in the specified region. New claims 27, 36, and 41 are anticipated because the protein encoded by the '022 patent comprises a fragment at least 40% identical to a fragment of SEQ ID NO: 2. New claim 44 is anticipated by the '022 patent because the '022 polynucleotide encodes a protein with 15 or fewer substitutions as compared to SEQ ID NO: 2. New claim 45 is anticipated because it encompasses molecules identified by hybridization. New claim 46 is anticipated because the protein encoded by the polynucleotide of the '022 patent is at least 90% identical to SEQ ID NO: 2. The sequence alignment is provided below.

US-08-820-970-1

Alignment Scores:

Pred. No.:	5.6e-120	Length:	780
Score:	1161.50	Matches:	208
Percent Similarity:	94.17%	Conservative:	2
Best Local Similarity:	93.27%	Mismatches:	12
Query Match:	92.55%	Indels:	1
DB:	3	Gaps:	1

US-10-092-925-2 (1-222) x US-08-820-970-1 (1-780)

Qy	1	MetLysSerHisTyrIle---ValLeuAlaLeuAlaSerLeuThrPheLeuLeuCysLeu	19
Db	72	ATGAAGTTACACTATGTTGCTGTGCTTACTCTAGCCATCCTGATGTTCTGACATGGCTT	131
Qy	20	ProValSerGlnSerCysAsnLysAlaLeuCysAlaSerAspValSerLysCysLeuIle	39
Db	132	CCAGAATCACTGAGCTGTAAACAAAGCACTCTGTGCTAGTGATGTGAGCAAATGCCTCATT	191
Qy	40	GlnGluLeuCysGlnCysArgProGlyGluGlyAsnCysProCysCysLysGluCysMet	59
Db	192	CAGGAGCTCTGCCAGTGCCGGCCGGGAGAAGGCAATTGCTCCTGCTGTAAGGAGTGCATG	251
Qy	60	LeuCysLeuGlyAlaLeuTrpAspGluCysCysAspCysValGlyMetCysAsnProArg	79
Db	252	CTGTGTCTTGGGGCCCTTTGGGACGAGTGCTGTGACTGTGTTGGTATGTGTAATCCTCGA	311
Qy	80	AsnTyrSerAspThrProProThrSerLysSerThrValGluGluLeuHisGluProIle	99
Db	312	AATTATAGTGACACACCTCCAACCTCAAGAGCACAGTGGAGGAGCTGCATGAACCGATC	371
Qy	100	ProSerLeuPheArgAlaLeuThrGluGlyAspThrGlnLeuAsnTrpAsnIleValSer	119
Db	372	CCTTCTCTCTTCCGGGCACTCACAGAAGGAGATACTCAGTTGAATTGGAACATCGTTTCT	431
Qy	120	PheProValAlaGluGluLeuSerHisHisGluAsnLeuValSerPheLeuGluThrVal	139
Db	432	TTCCCTGTTGCAGAAGAACTTTACATCATGAGAATCTGGTTTCATTTTGAAGAACTGTG	491
Qy	140	AsnGlnLeuHisHisGlnAsnValSerValProSerAsnAsnValHisAlaProPhePro	159
Db	492	AACCAGCCACACCACCAGAATGTGTCTGTCCCCAGCAATAATGTTTACGCGCCTTATTCC	551
Qy	160	SerAspLysGluArgMetCysThrValValTyrPheAspAspCysMetSerIleHisGln	179
Db	552	AGTGACAAAGAACACATGTGTACTGTGGTTTATTTTGATGACTGCATGTCCATACATCAG	611
Qy	180	CysLysIleSerCysGluSerMetGlyAlaSerLysTyrArgTrpPheHisAsnAlaCys	199
Db	612	TGTAAATATCCTGTGAGTCCATGGGAGCATCCAATATCGCTGGTTTCATAATGCCTGC	671
Qy	200	CysGluCysIleGlyProGluCysIleAspTyrGlySerLysThrValLysCysMetAsn	219
Db	672	TGCGAGTGCATTGGTCCAGAATGTATTGACTATGGTAGTAAAACTGTCAAATGTATGAAC	731
Qy	220	CysMetPhe	222
Db	732	TGCATGTTT	740

Allowable Subject Matter

13. Claims 3 and 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIMS 1, 4, 5, 7, 9, 13, 28-32, 34, 35, 37, 39, 40, 42, 43, AND 50-53 ARE ALLOWED. CLAIMS 3 AND 47-49 ARE OBJECTED TO. CLAIMS 2, 6, 7, 8, 10, 14-27, 33, 36, 38, 41, AND 44-46 ARE REJECTED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-

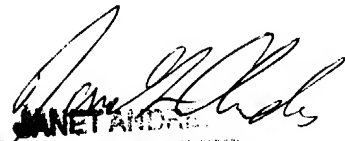
0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
Primary Examiner

14 July 2004


JANET ANDRES
PATENT EXAMINER